K954498

510(k) SUMMARY - FRONTLINE® OPIATES

Submitter Name:	Boehringer Mannheim GmbH
Submitter Address:	Sandhofer Str. 116 D-68298 Mannheim, Germany
Contact Person:	Richard Naples, Director Regulatory and Government Affairs
Phone Number:	(317) 576-3858
Fax Number:	(317) 845-2324
Date Prepared:	February 29, 1996
Device Trade Name:	FRONTLINE® OPIATES
Device Common Name:	Immunochromatographic test for opiates
Classification Name:	Opiate test system (per 21 CFR §862.3650)
Predicate Devices:	Emit® d.a.u. Opiate Assay; TDx® Opiates
Device Description:	FRONTLINE® OPIATES is a homogeneous immunochromatographic assay for use in the qualitative analysis of opiates in human urine. The assay is based on Gold Labeled Optical-read Rapid Immuno Assay (GLORIA) technology. Each test strip contains monoclonal antibodies reactive to a morphine derivative labeled with colloidal gold (conjugate) and morphine polyhapten, bulking agents, stabilizers and preservatives (solid phase). When immersed in urine, the test strip absorbs the volume of fluid necessary for the chromatographic reaction to occur. By capillary action, the urine passes through a compartment containing soluble conjugate which specifically binds to the opiate analyte. Excess conjugate is retained by the solid phase in a separate compartment. Only that conjugate with bound opiate analyte passes to the detection pad where a red-colored conjugate-analyte complex is viewed. The color developed on the detection pad is compared visually with a scale provided on the test strip vial. The intensity of the color developed correlates with the concentration of the analyte in the sample and the user may classify the analyte sample as: negative or positive (≥200 ng/mL).
Intended Use:	For use in the qualitative analysis of opiates in human urine at a cutoff concentration of 200 ng/mL.

26

Device Technological Characteristics and Comparison to Predicate Devices:

FRONTLINE® is based on Gold Labeled Optical-read Rapid Immuno Assay (GLORIA) technology. Each test strip contains monoclonal antibodies reactive to a morphine derivative labeled with colloidal gold (conjugate) and morphine polyhapten, bulking agents, stabilizers and preservatives (solid phase). When immersed in urine, the test strip absorbs the volume of fluid necessary for the chromatographic reaction to occur. By capillary action, the urine passes through a compartment containing soluble conjugate which specifically binds to the opiate analyte. Excess conjugate is retained by the solid phase in a separate compartment. Only that conjugate with bound opiate analyte passes to the detection pad where a red-colored conjugate-analyte complex is viewed. The color developed on the detection pad is compared visually with a scale provided on the test strip vial. FRONTLINE® OPIATES is a non-instrumented assay and requires no user calibration.

Emit® d.a.u. Opiate Assay is an enzyme immunoassay (EIA) based on the competition between analyte in the sample and analyte labeled with an enzyme for antibody binding sites. Results are measured with a suitable instrument based on absorbance changes compared to those generated by defined calibrators.

TDx® Opiates is a fluorescence polarization immunoassay (FPIA) in which the change in fluorescence polarization due to antibody binding correlates with the concentration of analyte in the sample. Results are measured with a suitable instrument and compared to those generated by defined calibrators.

Performance Data:

Comparison to EIA: A total of 728 metabolized urine samples were evaluated at three sites. 244 samples were FRONTLINE® positive and 482 were FRONTLINE® negative when compared to EIA and the confirmation method. One sample was classified as false positive and one sample was unavailable for confirmation analysis.

Comparison to FPIA: A total of 511 metabolized urine samples were evaluated at two sites. 191 samples were FRONTLINE® positive and 318 were FRONTLINE® negative when compared to FPIA and the confirmation method. Two samples were classified as false positive.

Conclusion:

FRONTLINE® OPIATES is substantially equivalent to other commercially-available opiate test systems.

57